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09/635,864	08/10/2000	Jeffrey M. Friedman	600-1-087CIP1	6312

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EXAMINER

SAUD, CHRISTINE J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/635,864

Applicant(s)

FRIEDMAN ET AL.

Examiner

Christine J. Saoud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-22, 28-59, 61-67 and 69-88 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 and 28-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 59, 61-67, 69-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

Claims 59, 61-67, 69-74 and 79 have been amended, claims 1-14, 23-27, 60 and 68 have been cancelled and claims 84-88 have been added as requested in the amendment of 07 January 2005. Claims 15-22, 28-59, 61-67, 69-88 are pending in the instant application. Claims 15-22, 28-58 remain withdrawn as being drawn to a nonelected invention, said election made without traverse in the Paper of 07 June 2002. Claims 59, 61-67, 69-88 are currently under examination in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 07 January 2005 have been fully considered but they are not deemed to be persuasive.

### ***Claim Objections***

Claims 69-88 are objected to because of the following informalities: the claims depend on a cancelled claim (claim 60). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

Claim 63 (and dependent claims 69-88) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant states that the specification provides an alignment of the human and mouse protein in Figure 4 and demonstrates that 83% of the amino acids are identical between the two proteins. The specification has been amended to reflect this calculation (139 amino acids out of a total of 167).

However, the claim is still rejected for a lack of written description because although the specification has provided human ob and mouse ob proteins and these two proteins share 83% amino acid sequence identity, this does not provide the basis for a claim to a nucleic acid encoding a polypeptide that has 83% or greater amino acid sequence identity to the sequence of the human or mouse (SEQ ID NO:2, 4, 5 or 6). The specification teaches two species of protein and the amino acid sequences of these proteins are described. However, what is being claimed is a genus of molecules which were never described in the instant specification. In fact, the single data point of 83% sequence identity does not support the genus claim to any protein having 83% or greater amino acid sequence identity to either the mouse or human sequence. This would encompass as much as 17% variability from the human and 17% variability from the mouse, and therefore 34% variability between different molecules. The single

disclosure of 83% is not a basis for the broad claim of the range 83% or greater amino acid sequence identity in the instant specification as originally filed.

Just because the human and mouse proteins differ by 17% does not provide a basis for a claim to any protein that varies by as much as 17% from the disclosed species. The specification does not provide an adequate written description of the claimed genus, and thus the claimed invention was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*Vas-Cath In. v. Mahurkar*, 19 USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for the purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present is a functional recitation of modulating body weight. There is no structure recited, except that the protein should be about 145 amino acids long. The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to

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practice has occurred, regardless of the complexity or simplicity of the method of isolation. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

With the exception of very particular amino acid sequences which are disclosed in the instant application, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide molecules and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of protein expression. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific molecular structure is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF=s were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) The instant claims are directed to a structure, which could be made, but for which, there is no written description. As in Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of

written description for the broad class because the specification provided only the bovine sequence.

Claims 59 and 69-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 has been amended to recite "a nucleic acid molecule that hybridizes under moderate stringency conditions". Applicant states that the claim has been amended "to provide hybridization conditions, as supported by the Specification" (see response at page 11). However, a review of the instant specification (specifically paragraph spanning pages 29-30) does not indicate a set of conditions which the skilled artisan could construe as being "moderate stringency conditions". This is because the degree of stringency depends on a number of variables, such as length of the nucleic acids, the degree of complementation, the temperatures used, the formamide concentration, the salt concentration, etc. These variables are pointed out in the specification, but there is no one set of conditions provided in the specification for what is intended to be "moderate stringency conditions", and based on the fact that results will differ based on what values are used for the different variables involved in hybridization, the metes and bounds of the claim cannot be determined. The claim is indefinite.

Claims 69-88 ultimately depend from claim 59 and therefore, they are indefinite as well.

Claims 61-67 (and dependent claims 69-88) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite “[A]n isolated nucleic acid molecule that encodes an OB polypeptide capable of modulating body weight and having one or more polymers attached thereto”. However, there is no indication of what is “capable of modulating body weight” – the polypeptide or the nucleic acid molecule. There likewise is no indication whether the polypeptide or the nucleic acid molecule has “one or more polymers attached thereto”. The claims could be read in either interpretation, and therefore, the metes and bounds of what is intended is not readily determined.

Claims 69-88 depend from claims which are indefinite, therefore, these claims are also indefinite.

As pointed out previously, if the polypeptide is to have the polymers attached thereto, the claims are not enabled for the full breadth of “polymers”. For example, polyethylene glycol is a common polymer which is attached to polypeptides in order to increase half-life, however, a nucleic acid cannot encode for polyethylene glycol, therefore, the claims are not enabled for the full scope of what is being claimed.

Applicant states that the claims have been amended to correct this deficiency, however, the amendment does not appear to have fixed the problem and the rejection is maintained.



### ***Double Patenting***

Claims 59, 61-67, 69-88 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 5,935,801 and claims 1-21 of U.S. Patent No. 6,309,853 for the reasons of record in the previous Office action.

U.S. Pat. No. 5,935,801 and 6,309,853 claim nucleic acids encoding OB polypeptides, which are the same as the OB polypeptides recited in the instant claims. However, some of the instant claims do include a recitation of "having one or more polymers attached thereto" and "optionally in a pharmaceutical carrier". As pointed out before, it is not clear if these limitations are to be placed on the protein or the nucleic acid. Regardless, the proteins of '801 and '853 use comprising language and therefore, conceivably include additional amino acids, such as polyamino acids. Therefore, the instant claims are not identical to those of '801, but they are encompassed by the claims of '801.

This is a provisional obviousness-type double patenting rejection.

Applicant did not respond to this ground of rejection except to state "[T]he issue will be readdressed by Applicants as such time as other patentability issues are settled". Applicant should be advised that failure to adequately address this ground of rejection in the next response could be construed as non-responsive.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*